

# EXHIBIT I

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Paper 13  
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SPECTRUM SOLUTIONS LLC,  
Petitioner,

v.

LONGHORN VACCINES & DIAGNOSTICS, LLC,  
Patent Owner.

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IPR2021-00851  
Patent 8,415,330 B2

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Before GEORGIANNA W. BRADEN, WESLEY B. DERRICK, and  
ROBERT A. POLLOCK, *Administrative Patent Judges*.

DERRICK, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314

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## I. INTRODUCTION

On April 26, 2021, Spectrum Solutions LLC (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–38 of U.S. Patent No. 8,415,330 B2 (“the ’330 patent,” Ex. 1001). Paper 1 (“Pet.”). Longhorn Vaccines & Diagnostics, LLC (“Patent Owner” or “Longhorn”) timely filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). With our authorization (*see* Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 8); Patent Owner filed a corresponding Sur-Reply (Paper 11).<sup>1</sup>

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition shows that there is “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). We deny *inter partes* review, for example, where a petition fails to identify “with particularity” the challenges or evidence supporting them. *Harmonic Inc. v. Avid Tech.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) as “requiring [*inter partes* review] petitions to identify ‘with particularity . . . the evidence that supports the grounds for the challenge to each claim’”); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence

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<sup>1</sup> Patent Owner filed duplicative copies of its Sur-Reply as Papers 10 and 11, which, absent a word-for-word comparison, appear identical but for minor differences in formatting. In an abundance of caution, we expunged Paper 10 in favor of the second-filed copy. Patent Owner subsequently indicated that the expunged version contained a formatting error. Ex. 3003.

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that supports the grounds for the challenge to each claim.” (quoting 35 U.S.C. § 312(a)(3))).

For the reasons discussed below, we deny institution of *inter partes* review.

*A. Real Parties-in-Interest*

Petitioner identifies itself, Spectrum Solutions LLC, as a real party-in-interest. Pet. 1. Petitioner further identifies two companies having a financial interest in, or potentially substantially affected by the outcome of, this proceeding: its parent company, Spectrum Holdco LLC, and Spectrum Intermediate LLC. *Id.* Petitioner does not expressly identify those companies as real parties-in-interest.

Patent Owner identifies itself, Longhorn Vaccines & Diagnostics, LLC, as the real party-in-interest in this proceeding. Paper 5, 1.

*B. Related Proceedings*

The parties identify a district court proceeding, *Longhorn Vaccines & Diagnostics, LLC v. Spectrum Solutions LLC*, C.A. No. 2:20-cv-00827 (D. Utah), as a related matter. Pet. 1; Paper 5, 1. The parties also identify *inter partes* review proceedings challenging patents at issue in the district court proceeding: IPR2021-00847 (U.S. Pat. No. 8,084,443), -00850 (U.S. Pat. No. 8,293,467), -00854 (U.S. Pat. No. 8,669,240), -00857 (U.S. Pat. No. 9,212,399), and -00860 (U.S. Pat. No. 9,683,256). Pet. 1; Paper 5, 1.

*C. The '330 Patent (Ex. 1001)*

The '330 patent is titled “Biological Specimen Collection and Transport System and Method of Use” and is directed to “compositions for isolating populations of nucleic acids from biological, forensic, and environmental samples” that can be used in formulations to “kill[]

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pathogens, inactivat[e] nucleases, and releas[e] polynucleotides from other cellular components within the sample, and stabiliz[e] the nucleic acids prior to further processing or assay.” Ex. 1001, codes (54), (57).

The ’330 patent states

In particular, the invention is directed to a one-step composition that a) inactivates viruses or microbes in the sample, b) lyses the biological cells or tissues to free the nucleic acids from cellular debris and extraneous biomolecules, c) protects the nucleic acids from degradation by endonuclease activity, and d) preserves the nucleic acids for subsequent isolation, detection, amplification, and/or molecular analysis.

*Id.* at 1:34–41. The ’330 patent further discloses that “[t]he ability to achieve all of these desirable functions in a single-step formulation, . . . is a particularly marked advantage over that presently available.” *Id.* at 3:47–50.

The ’330 patent discloses an embodiment of the composition as including

- a) one or more chaotropes (each preferably present in the composition an amount from about 0.5 M to about 6 M);
- b) one or more detergents (each preferably present in the composition an amount from about 0.1% to about 1%);
- c) one or more chelators (each preferably present in the composition in an amount from about 0.01 mM to about 1 mM);
- d) one or more reducing agents (each preferably present in the composition in an amount from about 0.05 M to about 0.3 M); and
- e) one or more defoaming agents (each preferably present in the composition in an amount from about 0.0001% to about 0.3%).

*Id.* at 4:26–37 (added formatting). Additional, optional components include buffers, short-chain alkanols, and additional compounds or reagents, including nucleic acids. *Id.* at 5:25–65. The ’330 patent also lists examples

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for each of chaotropes, detergents, chelators, reducing agents, defoaming agents, and other components. *Id.* at 4:38–5:65.

*D. Claimed Subject Matter*

Independent claims 1 and 31, reproduced below, are representative.

1. An aqueous composition that comprises: a chaotrope; a detergent; a chelator, a reducing agent; nuclease-free water, and a buffer with a pH of about 5 to about 7, wherein upon contact of the composition at ambient temperature with a biological sample suspected of containing a pathogen, nucleic acids and other macromolecules, creates an effective concentration of the composition that, in one step, disinfects said sample, inactivates nucleases of said sample, and extracts the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test.

Ex. 1001, 31:57–67.

31. A method of detecting a target sequence in a biological sample, comprising:

mixing, in one step, the biological sample with a composition at an ambient temperature creating an effective concentration of a chaotrope, a detergent, a chelator, a reducing agent, nuclease-free water, a short-chain alkanol, and a buffer with a pH of about 5 to about 7; that is effective to disinfect said sample, inactivate nucleases of said sample, and extract nucleic acids from other macromolecules of the biological sample such that a target sequence within the nucleic acids of the biological sample is detectable by a nucleic acid test; and can be maintained at ambient temperature for a period of time of at least 2 days;

performing the nucleic acid test on an aliquot of the mixture to detect the target sequence; and

detecting the target sequence in the biological sample.

*Id.* at 34:23–39.

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*E. Asserted Challenges to Patentability*

Petitioner challenges the patentability of claims 1–38 as follows

(Pet. 9):

<b>Claims Challenged</b>	<b>35 U.S.C. §<sup>2</sup></b>	<b>Reference(s)/Basis</b>
1–14, 18, 19, 21–23, 25, 27, 30–33, 35–38	§ 103(a)	Birnboim, <sup>3</sup> Farrell <sup>4</sup>
15–17	§ 103(a)	Birnboim, Farrell, Mori <sup>5</sup>
20	§ 103(a)	Birnboim, Farrell, Helftenbein <sup>6</sup>
14	§ 103(a)	Birnboim, Farrell, Yuan <sup>7</sup>
28, 29	§ 103(a)	Birnboim, Farrell, Birnboim2006 <sup>8</sup>
34	§ 103(a)	Birnboim, Farrell, Das <sup>9</sup>
24	§ 103(a)	Birnboim, Farrell, Das, Chen, <sup>10</sup> Wanh <sup>11</sup>

In support of its patentability challenge, Petitioner relies on the Declaration of Richard F. Taylor, Ph.D. (Ex. 1002).

<sup>2</sup> The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284, 287–88 (2011), revised 35 U.S.C. § 103 effective March 16, 2013. Because the challenged patent was filed before March 16, 2013, we refer to the pre-AIA version of 35 U.S.C. § 103.

<sup>3</sup> Birnboim, US 2004/0038269 A1, published Feb. 26, 2004. Ex. 1003.

<sup>4</sup> Robert E. Farrell, Jr., Ph.D., “RNA Methodologies: A Laboratory Guide for Isolation and Characterization,” (3<sup>rd</sup> Ed., 2005). Ex. 1026.

<sup>5</sup> Mori, WO 2005/111210 A1, published Nov. 24, 2005. Ex. 1011.

<sup>6</sup> Helftenbein, US 6,776,959 B1, Aug. 17, 2004. Ex. 1019.

<sup>7</sup> Yuan et al., “Statistical analysis of real-time PCR data,” BMC Bioinformatics 7:85–97 (2006). Ex. 1038.

<sup>8</sup> Birnboim, WO 2006/096973 A1, published Sept. 21, 2006. Ex. 1023.

<sup>9</sup> Das et al., US 2005/0123928 A1, published June 9, 2005. Ex. 1008.

<sup>10</sup> Chen et al., US 2007/0202511 A1, published Aug. 30, 2007. Ex. 1027.

<sup>11</sup> Wanh et al., WO 2004/104181 A2, published Dec. 2, 2004. Ex. 1022.

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## II. ANALYSIS

### A. *Level of Ordinary Skill in the Art*

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that

[a] person of ordinary skill in the art . . . would have had (1) a Ph.D. in microbiology, molecular biology, biochemistry, or related discipline; (2) at least two years of post-graduate experience in the area of nucleic acid extraction and analysis; and (3) experience with the development or use of nucleic acid extraction formulations, and the literature concerning nucleic acid extraction and analysis.

Pet. 7–8 (citing Ex. 1002 ¶¶ 34–35). Patent Owner does not dispute Petitioner’s proposed definition at this stage. Prelim. Resp. 7.

For purposes of this Decision, at this stage of the proceeding, we accept Petitioner’s proposed definition of the person of ordinary skill in the art, which is not substantively opposed by Patent Owner and appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the ’330 patent. *Cf. Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“the prior art itself [may] reflect[] an appropriate level” as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

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*B. Claim Construction*

In an *inter partes* review, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b). Under this framework, claim terms generally are given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification (including other claims), the prosecution history, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–19. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315.

Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (holding claim construction is not necessary when it is not “directed to, or has been shown reasonably to affect, the determination of obviousness”).

Neither Petitioner nor Patent Owner offer any position on the construction of any claim term. *See* Pet.; Prelim. Resp. 8.

On this record, and for purposes of this Decision, we decline to construe any claim terms beyond the limited extent we do so below in our analysis, because it is not necessary to do so in reaching our decision on institution.

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### *C. Principles of Law*

Petitioner challenges claims under 35 U.S.C. § 103. A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) if in evidence, objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

A party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools International, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (citations omitted). “In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic*, 815 F.3d at 1363 (citing 35 U.S.C. § 312(a)(3) as “requiring [*inter partes* review] petitions to identify ‘with particularity . . . the evidence that supports the grounds for the challenge to each claim’”). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v.*

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*Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

*D. Asserted Obviousness over Birnboim in View of Farrell*

Petitioner challenges claims 1–14, 18, 19, 21–23, 25, 27, 30–33, and 35–38 as unpatentable for having been obvious over Birnboim in view of Farrell. Pet. 10–53.

*1. Birnboim (Ex. 1003)*

Birnboim discloses “compositions and methods for preserving nucleic acids at room temperature for extended periods of time and for simplifying the isolation of nucleic acids,” most particularly, DNA or RNA from sputum or saliva. Ex. 1003 ¶¶ 2, 27. According to Birnboim, nucleic acid isolated can be that of the sputum or saliva donor or “from a bacterium or a virus that is residing in the buccal, nasal, or respiratory passages of the subject.” *Id.* ¶ 27; *see id.* ¶¶ 43 (defining “nucleic acid” as meaning “a chain of the nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, mitocho[n]dria, ribosomes, bacteria, or viruses”), 18 (“The nucleic acid to be preserved . . . can be . . . viral RNA.”), 27 (“If the nucleic acid is RNA, desirably it is mRNA or viral RNA.”), 45 (discussing quantitation of “high molecular weight nucleic acid (DNA, RNA, mRNA, or viral RNA)”), claims 7, 16.

Birnboim discloses “nucleic acid preserving compositions” for use in a one-step method to lyse nucleic acid-containing cells or viruses, release the nucleic acids into the composition, inactivate nucleases in the sample, and stabilize the extracted nucleic acid. *See id.* ¶¶ 11, 22, 27, 64, 114–122. Birnboim further teaches that the composition also reduces the viscosities of samples facilitating the extraction and recovery of nucleic acids. *See id.* ¶¶ 11 (stating the composition “contains an agent that rapidly reduces the

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viscous properties of mucin, greatly facilitating the extraction of nucleic acids contained within”), 64 (“The compositions of the invention can also include one or more reducing agents, which can reduce sample viscosity, thereby making nucleic acid recovery an easier process.”).

Birnboim explains:

When sputum is mixed with a composition of the present invention, cells are disrupted, nucleic acids are liberated from the cells, membranous material is solubilized, proteins are stripped from the nucleic acids, and protein digestion begins . . . . If transferred to a laboratory soon after collection, incubation at 55° C. for 4 to 16 hours is sufficient to allow the activated protease to digest the majority of protein to small peptides or amino acids. Under such conditions, nucleic acids and polysaccharides remain relatively intact.

Once digestion is complete, nucleic acid isolation can be performed using any technique known in the art.

*Id.* ¶¶ 84–85.

Example 1 discloses an embodiment wherein a subject spits saliva into a collection tube which is mixed with an equal volume of stock solution.

*Id.* ¶¶ 107–109. Once the container is capped and the contents shaken, the nucleic acid is “in an intermediate preserved state” and “can be maintained in a frozen state or at any temperature up to about 60° C.” *Id.* ¶ 110.

Alternatively, “[t]he container can be mailed back to the testing lab at room temperature.” *Id.* ¶ 111.

Example 3 discloses the collection and extraction of DNA using a “nucleic acid-preserving solution” comprising “33 mM TRIS-HCl, 0.67 M urea, 0.67 M LiCl, 0.6% sodium dodecyl sulfate, 3.3 mM CDTA, 30% ethanol, and 0.25 M sodium ascorbate, all adjusted to a final pH of 8.0.” *Id.* ¶¶ 114–122. In Example 4, Birnboim treats a portion of samples prepared using the nucleic acid-preserving solution with proteinase K, removes

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insoluble matter by centrifugation, and precipitates the DNA with ethanol prior to subjecting the DNA to agarose gel electrophoresis and ethidium bromide staining to find “the characteristic band of chromosomal DNA present in all samples.” *Id.* ¶ 117, Fig. 1. In Examples 5 and 6, Birnboim prepares “[m]inimally purified DNA” from samples prepared using the nucleic acid-preserving solution by centrifuging the samples to remove insoluble material and precipitating the DNA with ethanol prior to using polymerase chain reactions to detect the DNA. *Id.* ¶¶ 118–121.

## 2. *Farrell (Ex. 1026)*

Farrell is a laboratory guide describing the isolation and characterization of ribonucleic acids. Ex. 1026, Title. Farrell discloses that it was widely known that nucleases, which are enzymes that degrade nucleic acids, should be purged from solutions when trying to isolate RNA. *Id.* at 48–49. Farrell discloses that numerous compounds have been used to inhibit RNase activity including, vanadyl ribonucleoside complexes, RNasin, heparin, iodoacetate, polyvinyl (dextran) sulfate, cationic surfactant, macaloid and bentonite clays, and hydrogen peroxide. *Id.* at 50–53.

Farrell further teaches that it is known to treat “stock solutions and buffers prepared in the laboratory . . . with the potent chemical RNase inhibitor DEPC” or diethylpyrocarbonate. *Id.* at 55. Farrell notes that it “must be destroyed completely” since “[e]ven trace amounts of residual DEPC will result in chemical modification of the base adenine” and, thus, should not be added directly to cell suspensions or lysates containing RNAs to be purified. *Id.* Farrell discloses that there are additional “legitimate reasons” not to use DEPC in the laboratory and that making solutions with nuclease-free water is a more desirable alternative for solutions including nucleic acids. *Id.* at 57.

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### 3. Analysis

In asserting that claims 1–14, 18, 19, 21–23, 25, 27, 30–33, and 35–38 are obvious in view of Birnboim and Farrell, Petitioner relies on Birnboim’s disclosure of aqueous compositions for preserving nucleic acids in samples and on Farrell’s disclosure regarding the use of nuclease-free water.

Pet. 14–53. In short, Petitioner contends that Birnboim discloses aqueous compositions that include a chaotrope, detergent, chelator, reducing agent, and buffer together in amounts sufficient to accomplish the functional objectives recited in claim 1, that is, upon contacting a biological sample, “in one step, disinfect[ing] said sample, inactivat[ing] nucleases of said sample, and extract[ing] the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test.” *Id.* at 14–29. Petitioner similarly relies on Birnboim for claim 31, which recites a comparable “in one step” limitation. *Id.* at 46–50; Ex. 1001, 34:25–34 (claim 31 reciting “mixing, in one step, the biological sample with a composition . . . creating an effective concentration . . . that is effective to disinfect said sample, inactivate nucleases of said sample, and extract nucleic acids from other macromolecules of the biological sample such that a target sequence within the nucleic acids of the biological sample is detectable by a nucleic acid test”).

Patent Owner contends that Petitioner fails to establish a basis for the recited functional limitations. Prelim. Resp. 12–41. Patent Owner’s arguments include that Petitioner fails to show Birnboim’s composition extracts the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test and provides no basis for modifying the teachings to accomplish this

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requirement of the claims. *Id.* at 27–33. We focus our discussion on this dispositive issue.

Petitioner relies on “Birnboim disclos[ing] contacting, in one step, a sputum sample containing nucleic acids with an amount of Birnboim’s aqueous compositions.” Pet. 21. Petitioner relies on Birnboim disclosing that its “nucleic acid-preserving solution ‘preserves the nucleic acids at room temperature under ambient conditions for extended periods of time,’” including in its Examples 4–6. *Id.* at 20 (emphasis omitted) (citing Ex. 1003 ¶¶ 11, 115–122; Ex. 1002 ¶¶ 106–109).

As to extracting nucleic acids, Petitioner relies on Birnboim disclosing that its disclosed contacting of donor samples with its nucleic acid-preserving composition lyses cells such that nucleic acids are liberated from the cells. *Id.* at 22 (citing Ex. 1003 ¶ 84). Petitioner also relies on Birnboim disclosing, in its Examples 4–6, that “the samples are analyzed using either gel electrophoresis or PCR to detect nucleic acid from the samples” and that “PCR targets nucleic acids by using primers that hybridize to target sequences of the nucleic acid extracted from the sample[s].” *Id.* (citing Ex. 1003 ¶¶ 116–122; Ex. 1002 ¶ 109). Based on Birnboim’s disclosed lysing of cells and detection of nucleic acids, Petitioner contends that “Birnboim discloses that its nucleic acid preserving solution extracts ‘the nucleic acids from the other macromolecules such that a target sequence of the nucleic acid is detectable by a nucleic acid test.’” *Id.*

Petitioner repeats, a number of times, its contentions relating to the recited functional limitations, including that: “Birnboim discloses that the reagents provided in its nucleic acid-preserving solution reasonably would have been expected to create an effective concentration to disinfect cells . . . inactivate nucleases, and extract nucleic acids” (Pet. 22 (citing *id.* at 10–13

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(Section VI.A); Ex. 1002 ¶ 110)); “Birnboim’s denaturing agents lyse cells (which . . . extracts nucleic acid from cells)” (*id.* at 22–23 (citing Ex. 1003 ¶¶ 20, 41, 64, 67, 68, 73, 84)); and that “Birnboim[’s] Examples 4–6 establish that the nucleic acid is successfully extracted and preserved sufficiently to detect the nucleic acid via gel electrophoresis (Example 4) and via PCR (Examples 5 and 6),” “confirm[ing] that the amounts of the reagents used in the composition in Example 3 . . . extract nucleic acid” (*id.* at 23 (citing Ex. 1003 ¶¶ 116–122; Ex. 1002 ¶ 111)).

Petitioner’s position as to the extraction, in one step, of the nucleic acid such that a target sequence is detectable by a nucleic acid test, however, does not follow from Birnboim’s disclosure. While it is evident that Birnboim’s nucleic acid-preserving solution both lyses cells and preserves nucleic acids for extended periods of time such that the nucleic acid can later be detected, in each of Examples 4–6, there are additional steps before the nucleic acid test. In Example 4, Birnboim treats a portion of samples prepared using the nucleic acid-preserving solution with proteinase K, removes insoluble matter by centrifugation, and precipitates the DNA with ethanol prior to subjecting the DNA to agarose gel electrophoresis and ethidium bromide staining to find “the characteristic band of chromosomal DNA present in all samples.” Ex. 1003 ¶ 117, Fig. 1. In Examples 5 and 6, Birnboim prepares “[m]inimally purified DNA” from samples prepared using the nucleic acid-preserving solution by centrifuging the samples to remove insoluble material and precipitating the DNA with ethanol prior to using polymerase chain reactions to detect the DNA. *Id.* ¶¶ 118–121. These additional steps are consistent with Birnboim’s disclosure as a whole, which elsewhere describes its “nucleic acid preserving compositions” as facilitating the extraction and recovery of nucleic acids and teaches that “[o]nce

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digestion is complete, nucleic acid isolation can be performed using any technique known in the art.” *See id.* ¶¶ 11, 64, 84–85. Petitioner does not direct us to any teaching in Birnboim that treatment with the “nucleic acid-preserving solution,” standing alone, is sufficient to extract the nucleic acid from other components such that it is detectable by a nucleic acid test. Furthermore, there is neither any cogent argument nor testimony that Birnboim’s treatment meets the “in one step” limitation of independent claims 1 or 31. *See* Pet.; Ex. 1002. In assuming that this limitation is met by Birnboim, Petitioner also fails to direct us to any sufficient basis for modifying what is disclosed in Birnboim such that it meets the functional claim limitation requiring extraction such that the nucleic acid is detectable by a nucleic acid test.

Petitioner also contends that “the amounts of the chaotrope, detergent, chelator, and reducing agent in Birnboim’s composition reasonably would have been expected to perform the functions recited” because of the correspondence of Birnboim’s Example 3 with the recited ranges of chaotrope, detergent, chelator, and reducing agent in the ’330 patent’s claim 22 that depends from independent claim 1. Pet. 24.

Petitioner argues that “[b]y virtue of claim 22’s dependency from claim 1, the ’330 patent acknowledges that the specific concentration ranges recited by claim 22 are ‘an amount sufficient to’ carry out the claimed functions of claim 1, from which it depends.” *Id.* As support, Petitioner relies on *Alcon Research, Ltd. v. Apotex, Inc.*, 687 F.3d 1362 (Fed. Cir. 2012), as “holding that the concentrations recited in the dependent claims ‘must necessarily meet claim 1’s limitations of being therapeutically effective [amount]’ for accomplishing claim 1’s functional limitations.” *Id.* at 24–25 (alteration in original) (citing *Alcon Research*, 687 F.3d at 1367).

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As highlighted by Patent Owner, however, *Alcon Research* does not stand for the proposition Petitioner would have it support, namely, that compositions comprising multiple components with amounts of each component falling within the recited ranges necessarily meets the functional limitations. *See* Prelim. Resp. 32. Rather, *Alcon Research* more squarely addresses the circumstance where the base claim recites “using a ‘therapeutically effective amount’” of a particular compound, i.e., olopatadine, and the dependent claim recites a range for that particular compound. *Alcon Research*, 687 F.3d at 1367. Petitioner provides no cogent argument for extending *Alcon Research* to stand for the proposition that all compositions meeting the recited ranges of multiple components also meet the functional limitations of the base claim as required by its position. Pet. 24–25.

Additionally, as to the deviation in the concentration of reducing agent, 0.25 M rather than 0.5 mM–30 mM, in Birnboim’s Example 3, Petitioner relies on “Birnboim disclos[ing] . . . [it] would work,” but the function Birnboim performs, as discussed above, is not what is claimed. Pet. 25 (citing Ex. 1003 ¶¶ 13, 70). Similarly, Petitioner points to additional “prior art references [as] disclos[ing] nucleic acid preserving solutions for sputum, blood, and/or tissues having a chaotrope, detergent, chelator, and reducing agent within the ranges recited by claim 22,” and reproduces the ranges for components disclosed in Das (Ex. 1008) and Farrell (Ex. 1026), but provides no basis for the solutions, in one step, extracting the nucleic acids from other macromolecules such that a target sequence is detectable by a nucleic acid test, or that the compositions should be modified to ensure this function. *Id.* at 26–27 (citing Ex. 1008 ¶ 63; Ex. 1026, 89). Das discloses the cited lysis buffer in describing an improved process that includes

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extracting DNA from a treated clinical specimen and subsequently “purifying the DNA to improve yield by thorough precipitation by organic solvents.” Ex. 1008 ¶ 63; *see also id.* ¶ 89 (detailing further steps to purify DNA prior to its use for PCR amplification, including ammonium acetate precipitation with centrifugation to remove unwanted material, extraction with phenol and chloroform, and isopropyl alcohol precipitation with centrifugation). Farrell similarly discloses the use of the cited buffer as one step in a process, but further includes a CsCl ultracentrifugation step to obtain an RNA pellet, after which the RNA is dissolved in buffer, subjected to multiple organic extractions, and ethanol precipitated. Ex. 1026, 89–92. Petitioner also cites to Helftenbein (Ex. 1019) and Goldrick (Ex. 1009) for their disclosure of including various ranges of reducing agents, but again provides no basis for the recited one step extraction limitation being met. Pet. 26–27 (citing Ex. 1009, 7:33–47; Ex. 1019, 3:13–48; Ex. 1002 ¶¶ 115–118).

Petitioner contends that the cited overlap of ranges “demonstrate[s] that there is nothing inventive in the functional language recited by claim 1.” *Id.* at 27. In support, Petitioner cites *Perricone v. Medicis Pharmaceutical Corporation*, 432 F.3d 1368, 1377 (Fed. Cir. 2005), as “holding that prior art’s disclosure of a range that meets or overlaps specific ranges recited in dependent claims is sufficient to anticipate the broader ‘effective amount’ limitation of the independent claim,” and *E.I. DuPont De Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018), as holding that “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” Pet. 27. As highlighted by Patent Owner, however, *Perricone* involved methods of treatment grounded on “the topical

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application of ascorbic acid . . . in a fat soluble form,” a single effective ingredient, which reasonably differs from the present claims directed to compositions comprising multiple components. Prelim. Resp. 31–32; *Perricone*, 432 F.3d at 1371–72. Furthermore, *Perricone* relied on the limitations of the independent claim being anticipated because it was shown that the function required by the claim was inherently met when practicing the prior art method. *Perricone*, 432 F.3d at 1377. In contrast, Petitioner challenges the claims as obvious and provides no reasonable basis for the cited prior art inherently meeting the functional limitation of extracting the nucleic acid as set forth in claim 1. *See* Pet. Petitioner’s citation to *DuPont* is unavailing because it relates to the routine optimization of disclosed overlapping ranges, while Petitioner here relies on Birnboim’s Example 3 and the specific concentrations of 0.67 M urea and 0.6% sodium dodecyl sulfate disclosed. Pet. 25; *DuPont*, 904 F.3d at 1006.

Petitioner also contends that the claimed concentration ranges in a related patent, US 8,293,467 (Ex. 1036, “the ’467 patent”), would “reinforce that a [person of ordinary skill in the art] would reasonably expect Birnboim’s composition to meet the functions of ’330 patent claim 1.” Pet. 27–28. Petitioner states that “claim 1 of the ’330 patent and claim 1 of the ’467 patent, both recite a buffered mixture of a chaotrope, detergent, chelator, and reducing agent sufficient to, in one step, disinfect a sample by killing pathogens, inactivate nucleases, and extract nucleic acid from a biological sample to detect the presence of nucleic acids in the sample.” *Id.* at 28 (citing Ex. 1001, 31:57–67 (claim 1); Ex. 1036, 32:62–33:6 (claim 1 of the ’467 patent)). Petitioner then relies on ranges recited in the ’467 patent’s claim 2 in the same manner as it did for the recited ranges in the ’330 patent’s claim 22. *Id.* at 28–29.

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Petitioner's argument grounded on the '467 patent's claim 1 falls short for the reasons discussed above with respect to claim 22 in the '330 patent, namely, that it does not follow that all compositions meeting the recited ranges of multiple components also meet the "one step" functional limitations of the base claim. Further, Petitioner's contention that both claim 1 of the '330 patent and claim 1 of the '467 patent recite the same subject matter is not readily apparent. *Compare* Ex. 1001, 31:57–67, *with* Ex. 1036, 32:62–33:6. Claim 1 of the '467 patent recites "denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid" in its preamble, and recites these functions in the first two of three recited steps: "providing a mixture"; "contacting the biological sample with the mixture"; and "detecting the presence and identity of or absence of the pathogens in the biological sample." Ex. 1036, 32:62–33:6. The recited contacting step, thus, in one step, denatures proteins, inactivates nucleases, and kills pathogens. Petitioner provides no explanation how the '467 patent's claim 1 should otherwise be construed to require that the recited providing step, contacting step, and detecting step be combined into a single step, or whether that is even possible. Pet. 27–28.

In sum, Petitioner fails both to set forth a sufficient basis for Birnboim's nucleic acid-preserving composition meeting the functional requirement of, in one step, extracting the nucleic acid from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test and to provide a sufficient reason for one of ordinary skill in the art to modify Birnboim such that this functional requirement is met.

Independent claim 31, directed to a "method of detecting a target sequence in a biological sample," similarly requires "mixing, in one step, the

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biological sample with a composition . . . that is effective to . . . extract nucleic acids from other macromolecules of the biological sample such that a target sequence within the nucleic acids of the biological sample is detectable by a nucleic acid test.” Ex. 1001, 34:25–34. As with claim 1, Petitioner relies on Birnboim’s composition meeting this limitation. Pet. 48 (citing *id.* at 20–29 (Section VI.C.8); Ex. 1002 ¶¶ 183–184). And for the same reasons, Petitioner’s ground falls short.

*E. Asserted Obviousness over Birnboim in View of Farrell and Mori*

Petitioner challenges claims 15–17 as unpatentable for having been obvious over Birnboim in view of Farrell and Mori. Pet. 53–58. These claims further require “a surfactant or anti-foaming agent.”

Petitioner relies on Mori (Ex. 1011) for its teaching of a defoaming agent for the benefit of reduced foaming during “homogenizing treatment,” such as high-speed stirring or sonication. Pet. 53 (citing Ex. 1011, 58–59; Ex. 1002 ¶¶ 202–203); *see id.* at 54–57 (addressing claims 15 and 16), 57–58 (addressing claim 17).

Petitioner’s reliance on Mori fails to remedy the deficiency as to independent claim 1 from which claims 15–17 depend.

*F. Asserted Obviousness over Birnboim in View of Farrell and Helftenbein*

Petitioner challenges claim 20 as unpatentable for having been obvious over Birnboim in view of Farrell and Helftenbein. Pet. 58–59. Claim 20 further requires that the composition contain a “predetermined amount of a known nucleic acid sequence as an internal positive control for the nucleic acid test.”

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Petitioner relies on Helftenbein for its teaching of an internal standard, particularly an MS2-RNA for use as a positive control in a PCR test. *Id.* (citing Ex. 1019, 2:60–63, 6:27–8:36, 8:64–9:37; Ex. 1002 ¶¶ 216–220).

Petitioner’s reliance on Helftenbein fails to remedy the deficiency as to independent claim 1 from which claim 20 depends.

*G. Asserted Obviousness over Birnboim in View of Farrell and Yuan*

Petitioner challenges claim 26 as unpatentable for having been obvious over Birnboim in view of Farrell and Yuan. Pet. 59–60. Claim 26 further requires that “the target sequence is detectable in the composition at a concentration of about 0.1 ng or less.”

Petitioner relies on Birnboim’s Examples 5–6 disclosing “use [of] real-time PCR to detect target nucleic acid sequences” and on Yuan as “disclos[ing] that real-time PCR can detect target nucleic acid sequences at a beginning concentration of 0.08 ng/μL.” *Id.* at 59 (citing Ex. 1038, 4 (Table 1), 7 (Table 2), 10; Ex. 1002 ¶¶ 221–225). Petitioner contends, on this basis, that a person of ordinary skill in the art “would have had a reasonable expectation that Birnboim’s real-time PCR would successfully detect target sequence present in its composition at a concentration of 0.1 ng or less based on, e.g., Yuan.” *Id.* at 59–60.

Petitioner’s reliance on Yuan fails to remedy the deficiency as to independent claim 1 from which claim 26 depends.

*H. Asserted Obviousness over Birnboim in View of Farrell and Birnboim2006*

Petitioner challenges claims 28 and 29 as unpatentable over Birnboim in view of Farrell and Birnboim2006. Pet. 60–62. Claim 28 further requires that the “target sequence is detectable by the PCR at a Ct value that is lower than the Ct value of a control composition” and claim 29 that “the control

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composition is water.” Petitioner explains that “[t]he ‘Ct value’ refers to the earliest PCR amplification cycle where fluorescence is detected.” *Id.* at 60–61.

Petitioner relies on Birnboim2006 as teaching the use of water as a control composition, in particular a negative control, and for the resulting Ct value for PCR of a nucleic acid-preserving solution-containing sample being lower than that for the negative control. *Id.* at 60–62 (citing Ex. 1023, 19–22, Tables I–III; Ex. 1002 ¶¶ 226–232).

Petitioner contends that a person of ordinary skill in the art “would have been motivated to use water as a control composition in Birnboim’s PCR tests with a reasonable expectation of success.” *Id.* at 62.

Petitioner’s reliance on Birnboim2006 fails to remedy the deficiency as to independent claim 1 from which claims 27 and 28 ultimately depend.

#### *I. Asserted Obviousness over Birnboim in View of Farrell and Das*

Petitioner challenges claim 34 as unpatentable over Birnboim in view of Farrell and Das. Pet. 62–66. Claim 34 further requires that “the pathogen is an influenza virus or a tuberculosis bacterium.”

Petitioner highlights that Birnboim discloses that its composition can be used to preserve nucleic acids extracted from bacteria and viruses before contending that “Das also discloses its composition can be used to extract and preserve nucleic acids from bacteria, and more particularly for nucleic acid from tuberculosis-causing mycobacteria.” *Id.* at 63 (citing Ex. 1003 ¶ 27; Ex. 1008 ¶¶ 37–39). Petitioner further contends that Das’ composition meets the functional properties of claim 31 because it meets the concentration limitations of claims 11 and 22 (*id.* at 63–64 (citing *id.* at 20–29 (Section VI.C.8), 38–39 (Section VI.H), 39–40 (Section VI.I), 42–43 (Section VI.M), 46 (Section VI.Q); Ex. 1008 ¶¶ 63, 64, 89)), as well as

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because it specifically discloses that the functional limitations are met (*id.* at 64–65 (quoting Ex. 1008 ¶¶ 38 (“[A] strong chaotrope . . . ‘helps to inactivate all mycobacteria present in a clinical specimen, lyse tough mycobacterial cell [sic] and denature and remove proteins thus results into [sic] cleaner preparation of DNA.’” (emphasis omitted)), 39 (“[A] detergent in the formulation ‘helps in solubilization of cell wall lipid and of protein and thus result in complete lysis of the mycobacterial cell wall.’”))).

Petitioner also relies on Das’ “Examples 6 and 7 confirm[ing] that the extracted nucleic acid was amplified via PCR and analyzed using gel electrophoresis.” Pet. 65 (citing Ex. 1008 ¶¶ 91–98).

Petitioner contends that “[g]iven the references teach virtually the same compositions for the same use, a [person of ordinary skill in the art] would have been motivated to use Birnboim’s composition in view of Das for the specific purpose of extracting and preserving nucleic acid in a sample suspected of containing tuberculosis-causing pathogens.” *Id.* at 63. And, based on Das’ disclosed success using similar compositions, Petitioner also contends that a person of ordinary skill in the art “would have expected to successfully use Birnboim’s compositions, which are highly similar to Das’s compositions, to extract and preserve nucleic acids from a tuberculosis bacterium.” *Id.* at 65.

As discussed above in addressing the combination of Birnboim and Farrell, Petitioner fails to establish a sufficient basis for Birnboim’s nucleic acid-preserving composition meeting the functional requirement of, in one step, extracting the nucleic acid from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test. Petitioner’s reliance on Das does not remedy that deficiency. Petitioner cites Das’ paragraphs 38 and 39, but there is no apparent disclosure there that the

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DNA has been sufficiently extracted, in one step, such that a target sequence is detectable by a nucleic acid test. Ex. 1008 ¶¶ 38–39; *see also* Ex. 1002 ¶¶ 232–242 (Dr. Taylor’s corresponding testimony). Rather, to the contrary, the process set forth includes that “[t]he lysate is extracted once with alkaline phenol” and that the “[n]ucleic acid is precipitated from the aqueous phase with [an] equal volume of iso-propanol.” Ex. 1008 ¶ 39. Further, Das explains its use of phenol, stating “[i]t has been noticed that deproteinization by extraction with alkaline phenol is not unnecessary as claimed by many protocols” and that “[t]his simple step leads to removal of all proteins including the ones tightly bound to DNA and thus leads to cleaner nucleic acid preparation.” *Id.* Das’ Examples 6 and 7 that Petitioner relies on as “confirm[ing] that the extracted nucleic acid was amplified via PCR and analyzed using gel electrophoresis,” use samples that were subjected to additional purification steps subsequent to that utilizing Das’ lysis buffer. *Id.* ¶¶ 91 (“PCR reaction . . . [using] 2.0 µl DNA from the above preparation”), 89 (Example 4, titled “Extraction of DNA from Processed Clinical Specimens Using Modified Lysis Buffer,” and detailing further steps to purify DNA prior to its use for PCR amplification, including ammonium acetate precipitation with centrifugation to remove unwanted material, extraction with phenol and chloroform, and isopropyl alcohol precipitation with centrifugation).

Accordingly, Petitioner fails to remedy the deficiency as to independent claim 31 from which claim 34 ultimately depends.

*J. Asserted Obviousness over Birnboim in View of Farrell, Das, Chen, and Wanh*

Petitioner challenges claim 24 as unpatentable over Birnboim in view of Farrell, Das, Chen, and Wanh. Claim 24, depending ultimately from

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claim 1, recites particular compounds, i.e., particular chaotropes, reducing agent, chelator, detergent, buffer, anti-foam agent, and alcohols, in amounts according to specific concentration ranges.

Petitioner contends that “Chen is directed to ‘extraction compositions and methods for the rapid and efficient isolation of small RNA molecules from a biological sample’ and that “Wangh discloses compositions and methods ‘for preparing DNA or RNA molecules, or both, for amplification and detection or for other enzymatic processing of mixtures of DNA and RNA molecules that have been freed of bound proteins.’” Pet. 66 (citing Ex. 1027, Abstract; Ex. 1022, 6:9–15). Petitioner also contends that “[l]ike Birnboim and Das, both Chen and Wangh disclose aqueous compositions that include chaotropes, detergents, reducing agents, chelators, and buffers” and “Chen also discloses use of anti-foam agents and alcohols in its compositions.” *Id.* (citing Ex. 1027 ¶¶ 11–27; Ex. 1022, 8:8–18).

Petitioner contends that “Birnboim, in view of Das, Chen, and Wangh, disclose each of the claimed reagents and concentrations” and that “[b]ecause the prior art discloses the claimed ingredients and overlapping concentrations, claim 24 would have been obvious as a matter of routine optimization.” *Id.* at 66–67. Petitioner cites Das for disclosing guanidinium isothiocyanate and Chen for guanidine thiocyanate to meet the recited chaotrope; Chen for disclosing TCEP to meet the recited reducing agent; Wangh for disclosing sodium citrate and Das for disclosing EDTA to meet the recited chelator; Das for disclosing N-lauroyl sarcosyl for meeting the recited detergent; Das for disclosing Tris for meeting the recited buffer; Chen for reciting silicon-based antifoaming agents for meeting the recited silicone polymer; and Chen for disclosing ethanol for meeting the recited ethanol. *Id.* at 67 (citing Ex. 1008 ¶ 63; Ex. 1022, 8:8–18; Ex. 1027 ¶¶ 12–

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13, 23–24, 26). Petitioner argues that “it is an ‘unpatentable modification’ of the prior art to select particular concentrations within the ranges disclosed in the prior art” and that, therefore, “claim 24 is *prima facie* obvious.” *Id.* at 67–68.

Petitioner fails to set forth a sufficient basis for the combination that includes components from the different cited references because Petitioner merely identifies the various components and where they are disclosed in Das, Chen, and Wang. Pet. 67. Petitioner’s challenge, thus, fails to sufficiently establish why a person having ordinary skill in the art would combine the references in the manner required to arrive at the claimed invention. *See Innogenetics, N.V. v. Abbott Labs*, 512 F.3d 1363, 1374 (Fed. Cir. 2008) (holding that “some kind of motivation must be shown from some source, so that the jury can understand why a person of ordinary skill [in the art] would have thought of either combining two or more references or modifying one to achieve the patented [invention].”); *see also Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1366–67 (Fed. Cir. 2012) (citing *Innogenetics*, 512 F.3d at 1374) (“Even if the references disclosed all of the limitations . . . [the defendant] still needed to proffer evidence indicating why a person having ordinary skill in the art would combine the references to arrive at the claimed invention.”). While Petitioner and Dr. Taylor might arguably have set forth a sufficient basis for Chen and Wang to be analogous art, there is insufficient argument or evidence supporting the use of the particular components disclosed in the different references in combination as set forth by Petitioner. Pet. 66–68; Ex. 1002 ¶¶ 246–254.

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### III. CONCLUSION

After considering the evidence and arguments presented in the current record, we determine that Petitioner has failed to meet its burden for instituting *inter partes* review.

### IV. ORDER

It is:

ORDERED that the petition is denied and no *inter partes* review is instituted.

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**Subject:** IPR2021-00851: Institution Decision - Spectrum Solutions LLC v. Longhorn Vaccines & Diagnostics, LLC



**UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT TRIAL AND APPEAL BOARD**

Institution Decision Notice

**AIA Review No.:** IPR2021-00851  
**Petitioner:** Spectrum Solutions LLC of Draper, UT  
**Patent Owner:** Longhorn Vaccines & Diagnostics, LLC  
**Patent No.:** 8415330  
**Decision Date:** 11/18/2021  
**Submitted By:** PTAB, [Trials@uspto.gov](mailto:Trials@uspto.gov)

A decision whether to institute a trial has been entered in the above case.

Questions regarding this receipt should be directed to the Patent Trial and Appeal Board at 571-272-7822 or e-mail to [Trials@uspto.gov](mailto:Trials@uspto.gov).

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